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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,217	11/18/2003	Roger Harris	08457-002005	6038
20985 7590 09/21/2007 FISH & RICHARDSON, PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER HENLEY III, RAYMOND J	
			ART UNIT 1614	PAPER NUMBER
			MAIL DATE 09/21/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/717,217

**Applicant(s)**

HARRIS ET AL.

**Examiner**

Raymond J. Henley III

**Art Unit**

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 1-4, 6, 7, 9, 10, 14-17 and 21-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5, 8, 11-13 and 18-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
  - 2) ☒ Certified copies of the priority documents have been received in Application No. 08/909,513.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/26/2004</u> . | 6) <input type="checkbox"/> Other: _____  |

**CLAIMS 1-41 ARE PRESENTED FOR EXAMINATION**

Applicants' Preliminary Amendment filed March 24, 2004, Information Disclosure Statement filed July 26, 2004 and Response to Restriction Requirement filed July 5, 2007 have been received and entered into the application.

Accordingly, the specification at page 1 has been amended. Also, as reflected by the attached, completed copy of form PTO-1449, (1 sheet), the cited references have been considered.

***Election/Restrictions***

Applicants' election **without** traverse of the invention of Group III, claims 5-22 and of the species of insulin and beta-alanine is acknowledged.

Of claims 5-22, the claims which read on the elected species are claims 5, 8, 11-13 and 18-20, which are herein acted on the merits.

Claims 1-4, 6, 7, 9, 10, 14-17 and 21-41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species, there being no allowable generic or linking claim.

Insofar as Applicants have not traversed the species election and restriction requirement, as set forth in the Office action dated January 5, 2007, said election and requirement is hereby made **FINAL**.

While claims 6, 7, 9, 10 and 14-17 have been withdrawn from consideration. Upon a finding of allowable subject matter, consideration of further claimed species will be provided.

***Specification***

The specification at page 1, as amended, is objected to as being incomplete. The status of parent application S.N. 10/209,169, filed July 30, 2002, as now U.S. Patent No. 6,680,294 is absent. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

“The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent. A secondary purpose is to provide a clear measure of what applicants regard as the invention so that it can be determined whether the claimed invention meets all the criteria for patentability and whether the specification meets the criteria of 35 U.S.C. 112, first paragraph with respect to the claimed invention.”, (see MPEP § 2173).

The term "derivative" as set forth in claim 5, appearing in the expressions “an active derivative thereof” and “a chemical derivative of beta-alanine” is a relative term which renders the claim indefinite. In particular, “derivative” does not particularly point out the degree and/or type of derivation that a given compound may have in relation to the parent compound and still be considered a “derivative” as intended by Applicants. Applicants have failed to provide any specific definition for this term in the present specification. Lacking such a definition, the skilled

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artisan would not be reasonably apprised of the metes and bounds of the subject matter for which Applicants seek patent protection. Rather, a subjective interpretation of the claimed language would be required. However, as such is deemed inconsistent with the tenor and express language of 35 U.S.C. § 112, second paragraph, the claims are deemed properly rejected.

***Claim Rejection - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 5 and 11-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Michaelis et al., (U.S. Patent No. 5,561,110, cited by the Examiner), which teaches pharmaceutical compositions, suitable for oral or intravenous administration, comprising a beta-alanine dipeptide, such as carnosine, and insulin, (see the abstract, col. 3, lines 22-35, col. 4, lines 39-43 and 58-62 and col. 5, lines 13-52).

The designation in claims 12-13 of the composition being in different forms has been noted but is not seen to impart any further physical feature to the claimed composition that is not found in the compositions of the patentees.

***Claim Rejection - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

*I* Claims 5, 8, 11-13 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michaelis et al., (U.S. Patent No. 5,561,110), for the reasons set forth above, which are here incorporated by reference.

The differences between the above and the claimed subject matter lies in that the reference fails to contain a teaching of a carbohydrate in the composition or the dosage amounts as in present claim 18.

However, the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains because in oral compositions, such as tablets, it would have been obvious select various sugars, such as lactose, and employ it as a carrier material. Also, given the teaching in the reference at col. 5, lines 50-52, where the ingredient amounts are expressed in terms of the weight of the patient, it would have been obvious to vary the amounts of ingredients in the composition and

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the selection of any particular optimum amount is not seen to have been a matter outside the purview of one of ordinary skill in the art.

*II* Claims 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rihova et al., (U.S. Patent No. 6,071,888, cited by the Examiner) who teaches pharmaceutical compositions, in such forms as tablets, powders, drinking liquids, suppositories and in forms suitable for injection, (col. 3, lines 31-35), which comprise beta-alanine, (e.g., see the abstract). It is further taught that the composition may comprise a ribose compound, (a.k.a. a carbohydrate), (see col. 2, lines 33-38). The beta-alanine amount is taught to be from about 1% to about 45%, based on the weight of the composition, (col. 2, lines 44-48).

The designation in claims 12-13 and 20 of the composition being in different forms has been noted but is not seen to impart any further physical feature to the claimed composition that is not found in the compositions of the patentees.

The differences between the above and the claimed subject matter lies in that the reference fails to contain a teaching of the dosage amounts as in present claim 18.

However, the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains because the ingredient amounts would have varied in relation to the weight of the composition and it is not seen that the presently claimed amounts are any different those which would have been encountered in producing compositions of various weights.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

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improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 5, 8, 11-13 and 18-20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22-31 of U.S. Patent No. 6,426,361, cited by Applicants.

Although the conflicting claims are not identical, they are not patentably distinct from each other because from the construct of the patented claims, the instantly claimed elements in the form of a composition, would have clearly been obvious. Said elements being beta-alanine, insulin and optionally a carbohydrate and/or creatine.

The references cited on the attached form PTO-892 and not relied on have been cited to show the general state of the art.

Accordingly, for the reasons set forth above, the claims have been properly rejected. None of the claims are currently in condition for allowance.

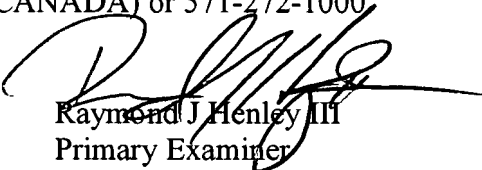


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Raymond J. Henley III  
Primary Examiner  
Art Unit 1614

September 14, 2007